

# **Part I.**

## **Revised OP Cumulative Risk Assessment**

## I. Revised OP Cumulative Risk Assessment

### A. Introduction

The Food Quality Protection Act of 1996 significantly amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). One of the major changes is the requirement that EPA consider risk posed by pesticides acting by common mechanism of toxicity.<sup>1</sup> For such groups of pesticides, EPA's Office of Pesticide Programs has treated cumulative risk, under FQPA, as the risk of a common toxic effect associated with concurrent exposure by all relevant pathways and routes.

Since the enactment of FQPA, EPA's Office of Pesticides Programs (OPP) has been working to develop new methodologies in a number of risk assessment areas. The steps necessary to complete the Revised OP Cumulative Risk Assessment were:

- Development of approaches for grouping chemicals by a common mechanism of toxicity (USEPA, 1999a) and
- Conducting aggregate (USEPA 1999c and 2001d) and cumulative risk assessments (USEPA 2000a and 2001a)

At each major step in development OPP consulted with the FIFRA Science Advisory Panel (SAP) to seek expert review, advice, and recommendations. We held several external peer review meetings with the SAP and asked for comment on our approaches to grouping chemicals based on common mechanism of toxicity, grouping chemicals for the purpose of cumulative assessment, improved methods for exposure assessment, approaches to aggregating food, drinking water and residential exposure and proposed models for combining these exposures. We also held several meetings with the FQPA Federal Advisory Committee Act (FACA) Groups of stakeholders (public interest groups, state agricultural agencies, pesticide industry representatives, growers, USDA and others) to present our methodologies as they were developed, and to seek comments and recommendations. All of the new science policies which are a foundation of this assessment were proposed for public comment. The work to develop the methodology was completed with the publication of the Revised Guidance Document for Cumulative Risk Assessment USEPA 2001a). The document was proposed for public comment on June 30, 2000 (65 FR 127:40644-40650). The SAP and public comments were reconsidered and the Guidance was revised in December, 2001. All of these documents played roles in preparation at the Preliminary OP Cumulative Risk Assessment which was issued

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<sup>1</sup>For details see The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7U.S.C. §§ 136 *et seq.*, and Federal Food, Drug, and Cosmetic Act (FFDCA) 21 U.S.C. § 346a.

in December 2001 and presented to the public in a technical briefing in January 2002. The assessment was reviewed by the SAP in February 2002. Public comment was also solicited for ninety days. The comment period closed in March 2002.

OPP proceeded with the methodology and risk assessment development in a step-by-step process. The approach to the risk assessment was evaluated using a case study of three organophosphorus pesticides. That assessment was reviewed by the SAP (September and December 1999 see FIFRA SAP 2000a,b), who recommended that OPP proceed with a more comprehensive case study. OPP developed the hazard, dose-response and exposure assessment for 24 OP pesticides and brought it to the SAP for comment in September and December of 2000 (FIFRA SAP 2001a,b). Based on the comments, the hazard and dose-response assessment was revised and again reviewed by the SAP in September of 2001 (FIFRA SAP 2001c). The SAP was very supportive of the approach, calling it both 'skillful' and 'creative.' The recommendations made by the September 2001 SAP were addressed in the Preliminary Risk Assessment. In February 2002, OPP brought the Preliminary OP Cumulative Risk Assessment to the SAP. Once again the panel was generally supportive of the preliminary document while suggesting some revisions. These revisions have been incorporated in this current document, the Revised OP Cumulative Risk Assessment.

Cumulative Risk Assessment is a complex analysis and OPP needs to emphasize that the results are not a collection of numbers or bright lines. Quantitative methods have been used throughout the analysis but the results need to be interpreted with a full understanding of the assumptions made and the uncertainties introduced by making these assumptions. As the regulatory managers and the stakeholders look for guidance in reading the document, it is especially important to consider the Risk Characterization Chapter of the Risk Assessment.